EXHIBIT F

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Mullins, et al. v. Ethicon, Inc., et al.*, 2:12-cv-02952, and all consolidated cases	

PLAINTIFFS' MOTION AND MEMORANDUM TO EXCLUDE THE OPINIONS AND TESTIMONY OF DEFENDANT ETHICON, INC.'s EXPERT STEVEN MACLEAN, PH. D., P.E.

Plaintiffs in the above-listed actions, pursuant to Federal Rules of Evidence 702, 403, and 104, as well as the U.S. Supreme Court decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), hereby respectfully moves this Court to exclude or limit the opinions and testimony offered by Defendant Ethicon, Inc.'s ("Ethicon") expert Steven Maclean, Ph.D., P.E.

INTRODUCTION

Ethicon designated Dr. Steven MacLean as an expert in this case. Like several other defense experts in this litigation, Dr. MacLean is employed by Exponent, Inc. Dr. MacLean – an Engineer – was hired by Exponent in 2011 to provide litigation services to industry clients like Ethicon and Johnson & Johnson.

> Q: You were hired by Exponent, in fact, according to this document, to help Exponent perform litigation services for industry clients, right?
> A: Correct.
> Q: Like Ethicon?
> A: Correct.
> Q: Like Johnson & Johnson?
> A: Correct.[1]

[1] Deposition of Steven MacLean, Ph.D., P.E., Sept. 29, 2015, at 34:23-35:6

Unfortunately, Dr. MacLean attempts to offer opinions well outside his expertise that are both unreliable and irrelevant. Specifically, the Defendants have designated Dr. MacLean to offer opinions in this case that: 1) Ethicon's TVT device is biocompatible; 2) the TVT device does not degrade;[2] and 3) that based on chemistry and a set of experiments performed at Dr. MacLean's direction, intentionally oxidized Prolene does not stain when exposed to Hematoxylin and Eosin (H&E) dyes.[3] Dr. MacLean is not qualified to offer opinions concerning histopathology, chemistry or the biocompatibility of the TVT device, the methodology used by Dr. MacLean to opine that the TVT does not degrade is unreliable, the experiments performed at the direction of Dr. MacLean are untrustworthy and unreliable and, finally, Dr. MacLean's opinions are litigation driven and unsound. For the reasons set forth herein, the Court should exclude or, at the very least, severely limit Dr. MacLean's opinions under *Daubert*.

ARGUMENT AND AUTHORITIES

The Court acts as gatekeeper to determine whether an expert's testimony is reliable and relevant. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 598 (1993); *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 141 (1999); Fed. R. Evid. 702. The proponent of expert opinion bears the burden of establishing its admissibility. *E.g., Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). Where the proponent fails to establish all of the prerequisites of admissibility, the exclusion of expert testimony is within the court's sound discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997). The proponent of expert testimony must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.* 137 F.3d 780, 783 (4th Cir. 1998).

[2] Exhibit 1 – Part 1 of the Expert Report of Steven MacLean, Ph.D., P.E.
[3] Exhibit 2 – Part 2 of the Expert Report of Steven MacLean, Ph.D., P.E.

The assessment of reliability involves a determination of whether the methodology or reasoning is valid and whether these factors can be applied to the facts of the case. *Daubert*, 509 U.S. at 592-593. An expert may testify only if "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702; *see Daubert*, 509 U.S. at 589. Ultimately, the trial court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

In order for a proffered expert's testimony to be reliable, there must be "a reasonable factual basis for [the expert's] testimony." *Teska v. Potlatch Corp.*, 184 F.Supp.2d 913, 919 (D. Minn. 2002). Opinions, which flow neither from background nor research, that have no independent standing and are formed only for purposes of litigation should be excluded. Courts are wary of such "expert" opinions:

> One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying....[I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is in the lab or the field, not the courtroom or the lawyer's office.

Daubert, 43 F.3d at 1317 ("*Daubert II*"); *see also* Lauzon v. Senco Prods., Inc. 270 F.3d 681, 687 (8th Cir. 2001) (citing *Daubert II*, noting impetus for opinion as a factor in considering the admissibility of expert testimony); *see also Wagner v. Hesston Corp.*, 2005 WL 1540135 (D. Minn. June 30, 2005), at *6 (attached as Exhibit 3) (citing *Daubert II*, noting that expert testing conducted almost entirely within the context of litigation "increase[d] the unreliability of [the

expert's] opinions").

As one Court has noted,

> both *Daubert* and *Kumho* make it clear tha the day of the expert, who merely opines, and does so on basis of vague notions of experience, is over. Experts are now held to a level of accountability that requires factual predicates, in historical fact, or in competent evidence, which allows a factfinder to independently verify the accuracy of the expert's results. Absent such reliable verification, the expert's opinion is not admissible.

Solheim Farms, Inc. v. CHN America, LLC, 503 F.Supp.2d 1146, 1150 (D. Minn. 2007).

Even if the expert is qualified and the testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." In re Ethicon, Inc. Pelvic Repair Sys. Products Liab. Litig., 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, the testimony must "fit" the case, *i.e.*, there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.*

I. This Court Should Exclude or, Alternatively, Limit the Expert Testimony of Dr. Steven MacLean

Dr. MacLean offers numerous opinions regarding the biocompatibility of Ethicon's TVT device. However, Dr. MacLean lacks the requisite knowledge, training, education and experience and is, therefore, wholly unqualified to offer these opinions. Moreover, the methodology employed by Dr. MacLean in reaching these opinions is unreliable.

During his deposition, Dr. MacLean testified that:

- He is not a medical doctor.[4]
- He is not a urogynecologist.[5]
- He does not hold himself out as a medical doctor or an expert in medical science.[6]

[4] Exhibit 4 - Deposition of Steven MacLean, Ph.D., P.E. at 36:7-9.
[5] *Id.* at 36:10-11.
[6] *Id.* at 36:12-14.

- He is not a veterinarian.[7]
- He is not a toxicologist and does not hold himself out as an expert in toxicology.[8]
- He is not a pathologist and is not an expert in pathology or histopathology analysis.[9]
- He does not hold any patents concerning polypropylene medical devices.[10]
- He testified he would not offer opinions about whether or not the TVT elicits an excessive, unacceptable inflammatory response.[11]
- He is not an infectious disease doctor.[12]
- Prior to this litigation, he has never consulted with a medical device manufacturer concerning the design of a mesh implant.[13]
- Prior to this litigation, he has never observed the implantation of surgical mesh devices.[14]
- Prior to this litigation, he has never testified as an expert regarding polypropylene material that is intended to be implanted in human beings.[15]
- Prior to this litigation, he has never analyzed explanted polypropylene mesh.[16]
- Prior to this case, he has never performed any pre-clinical testing of polypropylene mesh implants.[17]
- He is not a pre-clinical scientist.[18]
- He has never performed any biocompatibility assessments of the TVT mesh device.[19]
- He has never conducted any pre-clinical studies.[20]

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[7] *Id.* at 36:18-19.
[8] *Id.* at 36:20-24.
[9] *Id.* at 37:1-5.
[10] *Id.* at 37:6-8.
[11] *Id.* at 38:8-11.
[12] *Id.* at 38:14-16.
[13] *Id.* at 38:24-39:3.
[14] *Id.* at 39:11-14.
[15] *Id.* at 39:19-22.
[16] *Id.* at 40:7-11.
[17] *Id.* at 40:12-15.
[18] *Id. at* 40:16-17.
[19] *Id.* at 40:23:41:1.
[20] *Id.* at 41:7-9.

- He has never looked at medical devices that were explanted from animals to determine whether or not it was biocompatible.[21]
- His only experience in analyzing the biocompatibility of the Prolene used in the TVT device is in this case.[22]
- He has never performed any post-market testing of mesh implants prior to this case.[23]
- Prior to this litigation, he had never performed any failure analysis of a polypropylene suture.[24]
- Prior to this litigation, he has never studied the biocompatibility of polypropylene mesh for human tissue.[25]
- He has never published on the subject of biocompatibility of polypropylene mesh.[26]
- Prior to being retained as an expert in this case, he has never spoken or presented on the topic of polypropylene mesh.[27]
- He has never taught or lectured on the subject of polypropylene mesh.[28]
- He is not an expert on the biomechanical properties of the pelvic floor.[29]
- He is not a biologist or a molecular biologist.[30]
- He has never published any articles in a peer-reviewed journal concerning polypropylene mesh.[31]
- He has never published in peer-reviewed journals any study or test by him concerning polypropylene degradation.[32]
- He has never tested polypropylene medical devices that have been explanted from the body looking for degradation and, until this case, had never looked at any data concerning explanted polypropylene medical devices.[33]

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[21] *Id.* at 41:10-15.
[22] *Id.* at 41:22-42:1.
[23] *Id.* at 42:2-4.
[24] *Id.* at 46:17-47:4.
[25] *Id.* at 47:5-9.
[26] *Id.* at 47:10-13.
[27] *Id.* at 47:14-17.
[28] *Id.* at 47:18-20.
[29] *Id.* at 47:24-48:2.
[30] *Id.* at 48:3-6.
[31] *Id.* at 48:18-21.
[32] *Id.* at 48:22-49:10.
[33] *Id.* at 50:10-16.

- He has never published in the peer-reviewed literature on the subject of polypropylene.[34]
- He has only tested one Prolene mesh device in his entire career and has only reviewed data concerning Prolene mesh devices and this was all for the purpose of this litigation after being hired by the Defendants or Butler Snow.[35]
- He has never tested Prolene sutures prior to this case.[36]
- He is not a chemist and does not hold himself out as an expert in chemistry.[37]

A. Dr. MacLean Should be Precluded from Offering Opinions Concerning the Biocompatibility of the TVT device.

While admitting his lack of knowledge, training, education and experience in the above areas, Dr. MacLean attempts to offer opinions on these very topics. For example, in his expert report, Dr. MacLean opines that Prolene is biocompatible because "[t]he safety of PROLENE meshes has been demonstrated through a long history of clinical use in PROLENE sutures, as well as confirmatory cytotoxicity tests."[38] Dr. MacLean is an Engineer and as demonstrated from the above testimony does not have the necessary expertise or experience to offer opinions concerning the biocompatibility of Prolene meshes, Prolene sutures or Prolene resin.

Moreover, his opinions in this regard are unreliable. In order to offer opinions concerning the biocompatibility of Prolene, it is imperative that the expert first reach an opinion concerning the cytotoxicity of Prolene and to have also considered the relevant clinical studies. However, as Dr. MacLean testified, he has no opinion concerning cytotoxicity and did not adequately consider the relevant clinical studies concerning the safety of Prolene mesh, including the TVT device:

Q Are you offering any opinions in this case regarding the cytotoxicity of the TVT

[34] *Id.* at 51:17-21.
[35] *Id.* at 50:6-14.
[36] *Id.* at 50:18-20.
[37] *Id.* at 81:13-20.
[38] Exhibit 1 – Part 1 of the MacLean Report at pp. 20-21

material?

A No, I'm not.[39]
****
Q And you haven't looked at the clinical studies of the Prolene polypropylene mesh devices, correct?

A I just don't remember. I don't remember if I've -- it was not a focus of my work. So if I saw them, I just don't remember them.[40]

As demonstrated above, Dr. MacLean's opinions are beyond his qualifications and are unreliable as he failed to conduct a proper analysis of the relevant data, including the clinical studies. To be admissible, an expert must demonstrate an "application of his independent expertise" which Dr. MacLean does not and cannot do here. *Thorndike v. Daimler Chrysler Corp.*, 266 F. Supp. 2d 172, 185 (D. Me. 2003).

B. Dr. MacLean's Opinions Concerning the Regulatory History of Prolene Devices Should be Excluded

Similarly, Dr. MacLean spends a great deal of time in his expert report discussing the regulatory history of mesh devices yet Dr. MacLean is an Engineer and has not demonstrated that he is qualified to offer these opinions. By way of example, Dr. MacLean erroneously states that "…Ethicon obtained *approval* to market modified PROLENE, a mesh constructed of knitted filaments of extruded polypropylene, for repair of 'hernia and other fascial deficiencies'" and he cites to Ethicon, Inc.'s Modified PROLENE Polypropylene Mesh Nonabsorbable Synthetic Surgical Mesh 510(k) #962530 (emphasis added).[41] Dr. MacLean either does not have the expertise to understand and appreciate that this product was *cleared* rather than *approved* under the PMA process or he is intentionally misusing the term *approved* in an inappropriate effort to mislead the jury.

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[39] MacLean Dep. at 158:23-159:1
[40] *Id.* at 160:2-7.
[41] Exhibit 1 – MacLean Report at p. 21.

Nevertheless, Dr. MacLean is not qualified to offer opinions concerning the regulatory history of mesh devices and, as illustrated by Dr. MacLean's intentional or negligent misuse of the term "approved" throughout his report discussing products cleared through the 510(k) regulatory pathway, the probative value of the FDA regulatory history of mesh devices, including the TVT device, is substantially outweighed by unfair prejudice, confusing the issues and misleading the jury and should be excluded in this case pursuant to Fed.R.Evid. 403 as has been done by this Court in other cases.[42]

C. Dr. MacLean's Molecular Weight Opinions Based on Ethicon's Seven Year Dog Study Should be Excluded as Unreliable

In 1985 Ethicon began a dog study to specifically research the potential for Prolene to degrade *in vivo* over time.[43] Ethicon's scientists implanted dogs with Prolene size 5/0 dyed, Ethilon size 5/0 dyed, Novafil size 5/0 dyed and PVDF size 5/0 undyed.[44] The study was supposed to last 10 years and data was reported at different intervals (2 years, 5 years, 6 years 10.5 months and 7 years). The study ended prematurely after 7 years and Ethicon's scientists, using various techniques, again concluded at the 7-year interval that the Prolene 5/0 suture that they tested demonstrated evidence of degradation:

> **IR Microscopy**
>
> "IR spectra obtained for cracked PROLENE specimens (Figure A) showed possible evidence of slight oxidation (a broadened weak absorbance at about 1650 cm-1)."
>
> **Optical Microscopy and Scanning Electron Microscopy**
>
> "Degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking."[45]

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[42] This issue will be the subject of a motion *in limine* that will be filed in this case at the appropriate time.
[43] Exhibit 5 – ETH.MESH.09888068
[44] *Id.* at ETH.MESH.09888069
[45] Exhibit 6 – ETH.MESH.09888187-188

Despite this evidence, Dr. MacLean relies almost on the Gel Permeation Chromatrography (GPC) data obtained at the 7-year interval of the dog study for his opinion that Prolene does not degrade. However, Ethicon's GPC data is unreliable. As stated above, Ethicon implanted the dogs with Prolene 5/0 sutures; however, rather than run a control in 1985 of a Prolene 5/0 suture, Ethicon instead compared the GPC data of the explanted Prolene 5/0 suture (implanted in 1985 and explanted in 1992) to the "current" Prolene 4/0 suture that was available in 1992.[46]

As Dr. MacLean testified at his deposition, Ethicon should have determined the baseline of the test sample (i.e., Prolene 5/0) in 1985 when they started the dog study:

> Q. Yeah, I'm just trying to understand. So I'm not a scientist. So if there are variables or variability between one polypropylene to another polypropylene in the molecular weight, to -- if I'm going to do a study, I want to try to compare the same polymer as a control to the test article; is that right?
>
> A. If I want to look at -- are you suggesting that you're trying to investigate changes in molecular weight?
>
> Q. Yeah.
>
> A. And you need a baseline number?
>
> Q. Yeah.
>
> A. And the baseline would -- you would want the baseline to be representative of the original material; is that what you're suggesting?
>
> Q. Right, yeah.
>
> A. I'd say in general that makes sense.
>
> Q. Okay, because you want to -- you want to -- you want to reduce the variability?
>
> A. Well, you need a reference point.[47]

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[46] *Id.* at ETH.MESH.09888187 and 09888218-22
[47] MacLean Dep. at 238:5-239:1

However, in 1985, when Ethicon implanted the dogs with the Prolene 5/0 sutures, they never obtained a reference point in 1985 of Prolene 5/0 suture which Ethicon should have used as its control and its "baseline". Moreover, when asked whether he considered the molecular weight of a Prolene 5/0 suture, Dr. MacLean testified:

> Q. Have you looked -- have you looked at the molecular weight of a 5-0 Prolene suture and compared it to the molecular weight of a 4-0 Prolene suture?
>
> A. I don't recall.
>
> Q. Have you asked for data from Ethicon to show you what the molecular weight is in a 5-0 compared to a 4-0?
>
> A. No, I haven't asked for that.[48]
>
> ****
>
> Q. What is the molecular weight of the control 5-0 that was ran in 1985?
>
> A. I don't know if I've seen a document that says what the control of the 1985 5-0 is.[49]

Not only did Ethicon fail to use the appropriate control to eliminate the potential variability between the two different sutures but Dr. MacLean failed to even ask Ethicon's lawyers to provide him with data demonstrating what the molecular weight was of a 1985 Prolene 5/0 suture. Without demonstrating that the molecular weight of a 1985 Prolene 5/0 suture is the same as a 1992 Prolene 4/0 suture, Dr. MacLean is left to guess or assume the molecular weight is the same. *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318-19 (7th Cir. 1996) (stating that "the courtroom is not the place for scientific guesswork, even of the inspired sort). Guesswork, even educated hunchews, by an otherwise qualified expert is inadmissible. *Weis*gram v. Marley Co., 169 F.3d 514, 519-20 (8th Cir. 1999), aff'd 528 U.S. 440 (2000) (finding reversible error where trial court allowed expert witnesses to testify based on "rank

[48] *Id.* at 243:11-18.
[49] *Id.* at 247:14-17.

speculation"). Thus, Dr. MacLean should be excluded from offering opinions concerning the unreliable GPC data from the 7 year dog study.

D. Dr. MacLean's Cross-Sectional Schematic and Calculated Theoretical Total Molecular Weight (Mn) of Excised 5-0 PROLENE sutures should be excluded as unreliable

On pages 54-55 of his expert report, Dr. MacLean inappropriately extrapolates data from different studies to reach an unreliable opinion that Dr. Jordi's conclusions concerning the melt point of the Bellew explant is incorrect. Dr. Jordi conducted nano-thermal analysis on the surface of Ms. Bellew's explanted Prolift device and concluded that the drop in the melt point observed in Ms. Bellew's explanted Prolift device corresponded with a drop in the molecular weight of 4,500.[50] In an attempt to refute Dr. Jordi's findings, Dr. MacLean engages in math-magic first by using the melt point from the Bellew explant, then by assuming a crack depth of 4 microns, then by using Ethicon's dog study to demonstrate that the cracks are uniformly distributed over the surface of a 5-0 Prolene suture and finishes his magic by using the molecular weight data of the explanted 5-0 Prolene sutures from Ethicon's seven year dog study.

This analysis is flawed for several reasons. First, Dr. MacLean uses the molecular weight data from the dog study which is unreliable as discussed above. Second, he does not use the crack depth measurements from the dog study but instead "assumes" a crack depth of 4 microns from other studies while still using the molecular weight data from Ethicon's dog study. Yet, if the crack depths in the dog study only measured 2 microns, Dr. MacLean's opinion would be erroneous:

> Q. So if you assume 4 microns, it gets you outside of the standard deviation for the molecular weight?
> A. At 4 microns, it does, correct.
> Q. At 2 microns, it gets you closer to the bulk analysis, which would wash out the molecular weight changes on the surface, they'd be masked by the bulk?

[50] Dr. MacLean's Expert Report p. 54.

A. It could. Yeah, at some smaller crust thickness, you would be within the statistical confines of the original data.[51]

Additionally, Dr. MacLean erroneously states that the dog study demonstrated that the cracks were uniformly distributed over the entire surface of 5-0 sutures which is used by Dr. MacLean in his calculation. However, the dog study did not conclude that the cracks were uniformly distributed throughout the entire surface of Prolene 5/0 suture. The best evidence regarding the distribution of the cracks observed in the dog study comes from the 6 year 10.5 month report which demonstrates that "[a]pproximately 50% of the PROLENE suture surface was cracked due to degradation."[52] Rather than rely on credible science to support his opinions, Dr. MacLean cherry-picked his data in an attempt to mislead or confuse the jury. Accordingly, Dr. MacLean should be excluded from offering this unreliable opinion.

E. Dr. MacLean's Opinions Based on a Set of Experiments Performed at His Direction are Unreliable and Should be Excluded

Dr. MacLean offers several opinions which are based on data derived from a set of experiments performed by other scientists or laboratory technicians at Dr. MacLean's direction. The scientist who was primarily responsible for conducting these experiments was Stephanie Benight, Ph.D.[53] Dr. MacLean relies on the data generated from these experiments in an attempt to undermine the opinions of plaintiff's expert pathologist, Dr. Vladimir Iakovlev.

Specifically, Dr. Iakovlev has opined that, *inter alia*, the polypropylene used in the TVT device, known under Ethicon's brand name as Prolene, undergoes *in vivo* surface degradation. Dr. Iakovlev's opinions in this regard are based on his knowledge, training and experience as a pathologist, the body of scientific literature on this subject, including Dr. Iakovlev's own peer-

[51] MacLean Dep. at 278:23-279:8
[52] Exhibit 5 - ETH.MESH.09888100.
[53] MacLean Dep. at 83:22-84:4.

reviewed publications, and Dr. Iakovlev's own histological analysis of explanted TVT devices and other Ethicon devices manufactured with the same Prolene polypropylene material. Despite the overwhelming evidence to which Dr. Iakovlev relies, Dr. MacLean challenges a single finding made by Dr. Iakovlev during his histological analysis of explanted TVT or other Prolene mesh devices –that the degraded outer layer of explanted Prolene mesh fibers will stain using certain histological dyes.

However, the experiments relied upon by Dr. MacLean are unreliable for the following reasons:

- Dr. MacLean failed to develop and provide his team of scientists and laboratory technicians with a written protocol to follow prior to commencing the experiments;
- The scientists and lab technicians failed to contemporaneously record in a lab notebook or elsewhere the steps or procedures performed by each member of the team during the experiments which make the experiments, the data, and the opinions derived therefrom unreliable and untrustworthy;
- The sample size used in each of the experiments that Dr. MacLean relies was insufficient in size to draw reliable scientific opinions and prevented Dr. MacLean and his scientists from performing any meaningful or reliable statistical analysis;
- Samples that were used for histological staining were suspiciously not analyzed using Scanning Electron Microscopy (SEM) or Fourier transform infrared spectroscopy (FTIR) making Dr. MacLean's opinions untrustworthy and scientifically unreliable;
- The experiments performed were sloppy making any opinion derived therefrom unreliable and untrustworthy.

One experiment undertook to intentionally oxidize pristine TVT Prolene mesh with chemicals "according to the protocol published by Guelcher and Dunn" (hereinafter referred to as "Chemically Oxidized Prolene Mesh" or "Chemically-Treated Samples"). A second experiment was conducted to intentionally oxidize the TVT Prolene specimens using a Q-Lab QUV Accelerated Weathering Tester to irradiate the specimens with ultra violet radiation to induce photo-oxidation (referred to either as "QUV Oxidized Prolene Mesh" or "QUV-Treated

Samples").[54] In both of these experiments, certain samples were analyzed using different techniques to determine if the samples had become oxidized and degraded. Some samples were analyzed using Scanning Electron Microscopy (hereinafter referred to as "SEM") to determine whether any morphological changes consistent with oxidized-induced degradation occurred while other samples were chemically analyzed using a technique known as Fourier transform infrared spectroscopy (FTIR) to determine whether certain samples showed evidence of oxidation. Finally, one sample from each experiment – which was not analyzed using SEM or FTIR - was shipped to a third-party laboratory known as Histion, Inc. where the specimens were divided in half and embedded in either Paraffin or Resin and then stained with Hematoxylin and Eosin ("H&E") dyes.

i. Dr. Maclean did not develop and therefore his team did not follow a written protocol related to the experiment to intentionally oxidize a TVT sample using QUV-irradiation and his experiments were poorly documented making it impossible to verify the reliability of his experiments

Dr. MacLean did not develop any written protocols prior to commencing his experiment to intentionally oxidize TVT samples using QUV-irradiation which should have instructed his team of scientists and laboratory technicians on, *inter alia*:

1) The number of samples to be used in this experiment;
2) Which samples were to be treated with QUV-irradiation;
3) Which samples were to be analyzed using SEM;
4) Which samples were to be analyzed using FTIR; and
5) Which samples were to be sent to the third-party laboratory (Histion, Inc.) to be processed with Paraffin and Resin and then stained with H&E.

Without developing a written protocol prior to commencing his experiment, the reliability of his opinions was doomed from the outset. As this Court has previously held, "'Vigorous adherence to protocols and controls are the hallmarks of 'good science.'"

[54] Exhibit 2 - Part 2 of the MacLean Expert Report at p. 8.

Sanchez, 2014 WL 4851989 at *28 (citing *Black v. Rhone-Poulenc, Inc.*, 19 F.Supp.2d 592, 603 (S.D. W. Va. 1998)). In *Sanchez,* Dr. Mays admitted that he failed to prepare a written methodology before completing SEM testing. *Id.* at *27. Indeed, both Drs. Mays and Gido employed what the Court described as a "completely subjective cracking standard" for the purpose of their testing. *Id.* The Court deemed the testing of Drs. Mays and Gido unreliable, explaining that,

> Although Drs. Mays and Gido performed tests that re supported by literature, the haphazard application of these tests, errors, and changes to their report lead to the conclusion that their methodology is unreliable.

Id. at 28.

While Dr. Benight testified that they used "the protocol of the Plaintiff's experts, Dr. Guelcher and Dr. Iakovlev in the performance of these experiments,"[55] "protocol[s]…[from] hundreds of literature papers on QUV,"[56] and "the protocol of Dr. Reitman, et al., given in a conference presentation" two years prior to starting these experiments[57] none of these protocols addressed the critical issues above especially which samples from the experiments would be analyzed using SEM and FTIR and which sample would be sent for the histological preparation and staining. Dr. Benight could not identify if any of the supposed protocols were provided in writing for the specific purpose of the experiment conducted.[58]

As an illustration, in Dr. MacLean's expert report, he provides some SEM images of QUV oxidized mesh:[59]

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[55] Exhibit 7 - Deposition of Stephanie Benight, Ph.D. at 11: 24-25.
[56] Benight dep. at 14:20-22.
[57] *Id.* at 16: 10-15.
[58] Dr. Benight was asked multiple times if she had been provided any of these protocol in writing for use in this experiment. She testified that she had to recall the details from the Reitman conference presentation from two years prior. *Id.* at 17:5-9.
[59] Exhibit 2 - Part 2 of MacLean Report at p. 10.

However, it was determined during Dr. Benight's deposition that with regard to the QUV oxidation experiment, SEM images were only taken of samples 4, 5, and 6and FTIR was conducted only on samples 4 and 6.[60, 61] SEM would allow Dr. MacLean to determine if the samples showed cracks on the surface of the fibers indicative of oxidation while FTIR would provide additional evidence of oxidation. Suspiciously, however, SEM and FTIR were never performed on sample 2 – the only sample that was sent to Histion, Inc. for histological preparation and staining.[62] When asked about the decision not to analyze sample 2 using SEM and FTIR, Dr. Benight testified:

> Q. The decision was made not to look at Sample No. 2 using FTIR or scanning electron microscopy, correct?
> A. Sample 2 was sent to Histion for processing, embedding, and staining.
> Q. Who made the decision not to do SEM analysis and FTIR analysis on Sample No. 2?
> A. I don't recall, sir.[63]

The entire purpose of Dr. MacLean's experiments was to determine whether intentionally oxidized TVT mesh would stain. Thus, he should have determined whether the sample that was actually sent for histological staining was indeed cracked and oxidized. Dr. MacLean's failure to submit sample 2 for SEM and FTIR illustrates the problem of not developing and providing his team with a written protocol or, alternatively, this decision was done intentionally to mislead the jury. In either case, Dr. MacLean's experiment is unreliable

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[60] Benight dep. at 136:24-137:8.
[61] *Id.* at 139:8-15.
[62] *Id.* at 91:20-24.
[63] *Id.* at 262:2-9.

and should be excluded.

Similarly, it was impossible for Dr. Benight to identify what Chemically-treated samples were analyzed using FTIR and SEM.[64] Dr. Benight's inability to answer this question was the product of both not having a written protocol to follow before commencing the experiments and the failure on the part of Dr. MacLean's team to adequately document the procedures and steps taken during these experiments so the reliability could be independently verified.[65]

In *Black v. Rhone-Poulenc, Inc.,* District Judge Haden, made clear that *Daubert* scrutiny extends to whether a theory or technique can be and has been tested. 19 F.Supp.2d 592, 598 (S.D. W. Va. 1998). More specifically, the court determined that where independent reconstruction is made exceedingly difficult if not impossible, such facts weigh against admissibility. *Id.* at 599. Indeed, in that case, "poor record keeping" made independent reconstruction and re-test verification largely impossible with the study in question. *Id.* at 598. Dr. Maclean's lack of a written protocol and poor record keeping raises the same doubts with his own conclusions and should be excluded.

ii. Dr. Maclean's used an insufficient sample size in his experiments

Dr. Maclean's experiments are further unreliable as he only submitted one QUV-treated sample and one Chemically-treated sample to be processed histologically and stained with Hemotoxylin and Eosin (H&E).[66] In *Sanchez v. Boston Scientific Corp.*, this Court excluded the

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[64] *See e.g. Id.* dep. at 155:23-159:11

[65] *See e.g.* Benight dep. at 42:1-4 (Dr. Benight could not provide a date when the samples were divided); 53: 7 (When asked what other samples were in the QUV batch, Dr. Benight responded that it was "[m]ost likely numbers 1, 2 and 3."); 129:5-12 (When asked to identify an internal Exponent record that would verify which samples were treated using QUV-irradiation, Dr. Benight responded: "I have testified to that, sir."); 186:25-188:14 (Dr. Benight testified that Sample 6 was received from Histion, Inc. on Oct. 12, 2015; however, FTIR was performed by Exponent on Oct. 5, 2015 when questioned how the sample could be in two locations at the same time, Dr. Benight testified she or maybe somebody else cut a piece from Sample 6 before shipping Sample 6 to Histion in August 2015). 77:12-24 (FTIR analysis was performed on October 5, 2015 – after Dr. MacLean issued his report and subsequent to his deposition. There are no lab notebooks or other documentation verifying when the Samples were analyzed by FTIR other than the FTIR data generated on October 5, 2015).

[66] *Id.* at 91:20-24; 154:19-24.

testimony of Drs. Mays and Gido, two scientists put forth as experts in polymer science and similarly offering opinions relating to polypropylene degradation, in part for their failure to control for error or bias. 2014 WL 4851989 at *24 (S.D. W.V. Sept. 29, 2014). As this Court explained, "[t]he small sample size and Drs. Mays and Gido's failure to determine the statistical significance of their results call into the question the reliability of their methods. Although *Daubert* is a flexible inquiry, these facts weigh heavily against the reliability of their opinions." *Id.* at *27. Further, the Court observed that Drs. Mays and Gido's failure to provide an explanation as to whether a sample size is representative inhibits assessing the potential rate of error inherent in the expert's observations. 2014 WL 4851989 at *26 (citing *Lewis v. et al. v. Ethicon, Inc.*, No. 2:12-ccv-04301, 2014 WL 186872, at *8 (S.D. W. Va. Jan 15, 2014). Dr. Maclean's opinions based on his two experiments should be excluded for precisely the same reason. In fact, Dr. Benight, confirmed they "didn't perform any statistical analysis as part of this investigation that was summarized in Dr. Maclean's report."[67] For the same reasons Drs. Mays and Gido were excluded in the *Sanchez* case, Dr. MacLean's opinions based on a single sample in each of his experiments should be excluded here.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court grant their Motion to Exclude or, Alternatively, Limit the Opinions and Testimony of Dr. Maclean, Ph.D., P.E.

[67] *Id.* at 88:4-10.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 22, 2015, a true and correct copy of this Motion was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notifications of such filing to the CM/ECF counsel of record.

/s/ Bryan F. Aylstock